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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,262	01/14/2004	Venkateswarlu Karicheti	MPI03-007P1RNOMNIM	6482
30405	7590	09/21/2005	EXAMINER	
MILLENNIUM PHARMACEUTICALS, INC. 40 Landsdowne Street CAMBRIDGE, MA 02139			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/757,262

Applicant(s)

KARICHETI ET AL.

Examiner

Anand U. Desai, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 23 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 23 and 25-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20050630</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. This office action is in response to Amendment filed on June 30, 2005. Claims 6, and 24 have been cancelled. New claims 25-31 have been added. Claims 1-5, 7, 23, and 25-31 are currently pending and are under examination.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on June 30, 2005 is being considered by the examiner.

#### **Withdrawal of Rejections**

3. The rejection of claims 3-5, and 23 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph as being indefinite is withdrawn.

#### **Maintenance of Objections and Rejections**

#### ***Specification***

4. The abstract of the disclosure is objected to because the interpretation of the numerical identifier 8263, can be misinterpreted as eight thousand two hundred and sixty three genes that were analyzed for differential expression. Suggest using the enzyme name, Carboxypeptidase Z, in place of the identifier 8263. Correction is required. See MPEP § 608.01(b).

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

Art Unit: 1653

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4, 7, 23, 25-28, 30, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Song and Fricker (Journal of Biological Chemistry, Vol. 272, No. 16, pages 10543-10550 (1997)).

Song and Fricker disclose the cloning and expression of Human Carboxypeptidase Z (CPZ), a novel metallocarboxypeptidase. Song and Fricker tested CPZ activity in Sf9 cells with a variety of compounds that inhibit other members of the metallocarboxypeptidase gene family. The CPZ activity was inhibited by the chelating agent 1,10-phenanthroline (Table IV). The active site-directed inhibitors 2-mercapotmethyl-3-guanidinoethyl-thiopropionic acid (MGTA) and guanidinoethylmercaptosuccinic acid (GEMSA) inhibit CPZ activity at 1mM concentrations (Table IV, see also last paragraph of Results section). The binding of an inhibitor to the active site would compete with the endogenous substrate and therefore would be reasonably interpreted to be a competition binding assay (current application, claims 7, and 30). Therefore, Song and Fricker disclose a method of combining a candidate compound with CPZ and identifying if the candidate compound inhibits CPZ activity (current application, claims 1-4, 7, 23, 25-28, 30, and 31).

7. Claims 1-5, 7, 23, and 25-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Mack et al. U.S. Publication 2004/0076955 A1 (Effective filing date=July 3, 2001).

Mack et al. disclose the use of nucleic acid, polypeptides, and antibodies thereto that are involved in bladder cancer. The invention also relates to methods for identifying and using

Art Unit: 1653

agents and/or targets that inhibit bladder cancer (see page 1, paragraph 2). The present invention provides a method for identifying a compound that modulates bladder cancer-associated polypeptide, the method comprising the steps of: (i) contacting the compound with a bladder cancer-associated polypeptide, the polypeptide encoded by a polynucleotide that selectively hybridizes to a sequence at least 80% identical to a sequence as shown in Tables 1A-13; and (ii) determining the functional effect of the compound upon the polypeptide. In one embodiment, the functional effect is an enzymatic effect, and the functional effect is determined by measuring ligand binding to the polypeptide (see page 2, paragraphs 31-34, and claim 19). Table 8A discloses carboxypeptidase Z as a gene predictive of bladder cancer progression (see page 122, 14<sup>th</sup> line down, current application, claim 1-5, 7, 23, and 25-31).

#### Response to Remarks

8. Applicant's arguments filed June 30, 2005 have been fully considered but they are not persuasive. In response to applicant's arguments, the recitation "capable of treating urinary incontinence" and "capable of treating benign prostatic hyperplasia" have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Song and Fricker disclose a method of combining a compound, particularly an active site-directed inhibitor with Carboxypeptidase Z, therefore the

Art Unit: 1653

inhibitor would be expected to bind the enzyme, Carboxypeptidase Z (current application, SEQ ID NO: 104). Therefore, Song and Fricker anticipate the method currently being claimed. In addition, Mack et al. also disclose the method for identifying a compound comprising the steps of contacting a compound with Carboxypeptidase Z and determining the functional effects on Carboxypeptidase Z (see 102(e) rejection above for citation). Thus, Mack et al. anticipates the method currently being claimed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

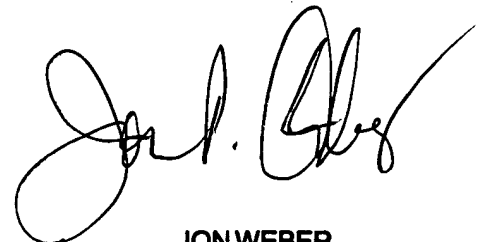
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 17, 2005



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**